



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,289	01/02/2004	Syed F.A. Hossainy	50623.363	2385
7590 Cameron K. Kerrigan Squire, Sanders & Dempsey L.L.P. Suite 300 1 Maritime Plaza San Francisco, CA 94111		04/23/2007	EXAMINER HAGOPIAN, CASEY SHEA	
			ART UNIT 1615	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/751,289	HOSSAINY ET AL.
	Examiner Casey Hagopian	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 January 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 39,40,42-50 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) 39,40 and 42-50 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 65 and 67 is/are rejected.
- 7) Claim(s) 66 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 1/9/2007.

Response to Arguments

Applicant's arguments, with respect to the rejection of claims 65-67 under 35 USC 102, have been fully considered and are persuasive. The rejection of claims 65-67 under 35 USC 102 has been withdrawn. However, after further consideration a new rejection has been made in view of Reich et al. (USPN 5,962,620) (see *New Rejections*).

Applicant's amendment, with respect to the rejection of claims 65-67 under 35 USC 112, renders the rejection moot. Accordingly, the rejection of claims 65-67 under 35 USC 112 has been withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Reich et al. (USPN 5,962,620) teaches several configurations of multilayer coatings for the use in stents that include primer regions and drug regions comprising a drug and a

polymer (i.e. reservoir regions) as well as the specific primer material polyisocyanate (cols. 19-20). Thus, the disclosures of Reich render the instant claims anticipated.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 65 and 67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24 and 25 of U.S. Patent No. 6,790,228 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application contains "comprising" language which allows for other ingredients. Both the application and patent are drawn to an implantable medical device (e.g. stents) comprising a coating, wherein the coating comprises a) a reservoir layer comprising a polymer and a drug and b) a primer region

free from any drugs comprising a material selected from the group consisting of polyisocyanates, unsaturated polymers, high amine content polymers, acrylates, polymers containing a high content of hydrogen bonding groups, and inorganic polymers.

Claims 65 and 67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 and 12 of U.S. Patent No. 6,908,624 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application and the patent both contain open language such as "comprising" or "including" which allows for other ingredients. Both the application and patent are drawn to an implantable medical device (e.g. stents) comprising a coating, wherein the coating comprises a) a reservoir layer comprising a polymer and a drug and b) a primer region wherein the primer region can contain an acrylate.

Allowable Subject Matter

Claim 66 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. It is suggested that the limitations of claim 66 be imported into claim 65 so that the claim reads, "An implantable device comprising a coating, wherein the coating comprises: a) a reservoir layer comprising a polymer and a drug dispersed in the reservoir layer; and b) a primer region free from any drugs located between the reservoir layer and the surface of the device, the primer region comprising

Art Unit: 1615

a material selected from a group consisting of polyester diacrylates, polycaprolactone diacrylates, polytetramethylene glycol diacrylate, polyacrylates with at least two acrylate groups, polyacrylated polyurethanes, triacrylates, and any combination thereof".

Conclusion

Claims 65 and 67 have been rejected and claim 66 has been objected to; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1615

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Hagopian

Casey Hagopian
Examiner
Art Unit 1615

Carlos A. Azpurua
CARLOS A. AZPURUA
PRIMARY EXAMINER
GROUP 1500